

Case 3:23-cv-0

SEALED

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

Jonathan Hamer ex. rel. UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE STATE OF MICHIGAN, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE STATE OF WISCONSIN, THE COMMONWEALTH OF MASSACHUSETTS, THE COMMONWEALTH OF VIRGINIA, THE DISTRICT OF COLUMBIA, THE CITY OF CHICAGO, THE STATE OF CONNECTICUT, THE STATE OF COLORADO, THE STATE OF MARYLAND, THE STATE OF IOWA, and THE STATE OF WASHINGTON

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CIVIL ACTION NO. 3:23-cv-1472-G

Plaintiffs

v.
BOND PHARMACY, INC. a DELAWARE
CORPORATION, trading as ADVANCED
INCLUSION SOLUTIONS

Defendant

JURY TRIAL DEMANDED

FIRST AMENDED QUI TAM COMPLAINT

1. Plaintiff and Relator Jonathan Hamer (“Relator”) hereby files this qui tam complaint pursuant to the False Claims Act, 31 U.S.C. § 3729 et seq. and individual state statutes identified herein (each an “FCA” and the False Claims Act “the FCA”) on behalf of the United

States and the state government entities (“State Plaintiffs”) as well as for himself individually under § 3730(h) of the FCA.

2. As required, Relator has provided a disclosure statement in accordance with § 3730(e)(4)(B) and § 3730(b)(2) of the FCA and the relevant provisions of the State Plaintiffs’ individual false claims acts identified herein.

3. The footnotes contained in this qui tam complaint should be read and considered as part of the allegation set forth in such paragraphs.

I. SUMMARY OF CLAIMS

A. Background and Overview

4. Defendant Bond Pharmacy, Inc., is a Delaware corporation, trading as Advanced Infusion Solutions (“AIS”). AIS provides, inter alia, targeted drug delivery (“TDD”) for drug medications it “compounds” through infusion therapy, by dispensing and administering its compounded medication with implantable intrathecal pumps manufactured by a third party.

5. Relator was hired in early 2018 by AIS and served as Director of Pharmacy and eventually Pharmacist in Charge (“PIC”) of the AIS Dallas, Texas facility from its opening through the Summer of 2021.

6. Relator observed repeated areas of regulatory noncompliance, including, inter alia, faulty construction methods and conditions that lead to systematic unsafe conditions as well as a chronic failure to maintain the Dallas facility in a safe and sterile condition as required by applicable laws noted herein. AIS was, and has been aware, of these conditions.

7. Collectively, this malfeasance has caused significant and substantial unsterile and unsafe conditions in the Dallas facility in general and in the “clean room”¹ where the drug compounding occurs, leading to adulteration of the drugs and loss of efficacy of the drugs being compounded.

8. "Drug compounding" refers to "the process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002). Though a compounded drug qualifies as a "new drug" under the Food, Drug and Cosmetic Act (FDCA) 21 U.S.C. § 321(p), the Food and Drug Administration (“FDA”) has historically left regulation of compounded drugs to the states. Over time, however, FDA grew concerned that some pharmacies were compounding drugs at levels that rendered the pharmacies akin to drug manufacturers.

9. To address these concerns, Congress added Section 503A to the FDCA. See 21 U.S.C. § 353a ("Section 503A"). Section 503A sets forth certain conditions that must be satisfied for compounded drugs to be exempt from the vast regulatory framework in the FDCA that would otherwise govern new drugs. First, there is a general exemption for drugs that are "compounded for an identified individual patient based on the receipt of a valid prescription or a notation." Section 503A then imposes additional requirements for such compounded drugs that are

¹ Clean rooms are classified according to the cleanliness level of the air inside the controlled environment measured by the size of particles per cubic meters of air. The primary authority in the United States for classification of clean rooms is the ISO classification system referred to as ISO 14644-1. This ISO standard includes these clean room classes: ISO 1, ISO 2, ISO 3, ISO 4, ISO 5, ISO 6, ISO 7, ISO 8 and ISO 9. ISO 1 is the “cleanest” class and ISO 9 is the “dirtiest” class. Even if it is classified as the “dirtiest” class, the ISO 9 clean room environment is cleaner than a regular room. The most common ISO clean room classes are ISO 7 and ISO 8.

distributed interstate. Specifically, a drug may be compounded pursuant to Section 503A's general exemption only if it falls into one of two categories:

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding (“MOU”) with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

9. An MOU under Section 503A describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FDCA requiring: (1) compliance with current good manufacturing practice. (21 U.S.C. 351(a)(2)(B)) (“Section 501(a)(2)(B)’); (2) labeling with adequate directions for uses (21 U.S.C. 352(f)(1)) (“Section 502(f)(1)’); (3) FDA approval prior to marketing (21 U.S.C. 355) (“Section 505”).

10. AIS has obtained licenses in all 50 states, representing itself in the license applications and registration as meeting the conditions to be a Section 503A pharmacy. As such, AIS as a Section 503A facility must compound its drug products in accordance to patient specific prescriptions and is required by the state boards of pharmacy to comply with US Pharmacopeia (“USP”) guidelines.

11. USP is an independent, scientific nonprofit organization focused on standards to build trust in the supply of safe, quality medicines. USP General Guidelines, Chapter 795 (non

sterile), Chapter 797 (sterile) and Chapter 800 (hazardous). These standards apply to all healthcare personnel who receive, prepare, administer, transport or otherwise come in contact with hazardous drugs and all the environments in which they are handled.

12. Chapter 800 describes the specific requirements and responsibilities of personnel handling hazardous drugs; facility and engineering controls; procedures for deactivating, decontaminating and cleaning; spill control; and documentation.

13. Compounded medications made without the guidance of standards maybe sub-potent, super-potent or contaminated, exposing patients to significant risk of adverse events or even death. USP developed standards for compounding sterile medications to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing. Specifically, USP Chapter 797 set forth standards and guidelines for pharmaceutical compounding of sterile preparations to ensure the quality and safety of compounded sterile drug preparations. These are medications that are administered intra-ocular and intrathecal. USP Chapter 797 standards apply to all pharmacies that produce compounded sterile preparations (“CSPs”), including those in hospitals, retail and standalone settings. USP Chapter 797 provides the standards under which regulatory agencies, particularly the state-level departments of public health and board of pharmacy, can pursue pharmacies for unsafe compounding practices. Chapter 797 was developed to prevent patient harm and fatalities from microbial contamination, excessive bacterial endotoxins, large content errors in the strength of correct ingredients, and the inclusion of incorrect ingredients in CSPs.

14. Violations of the FDCA by AIS also include adulterated drug products. Drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have been contaminated with filth, or rendered injurious to health,

causing AIS products to be adulterated in violation of Section 501(a)(2)(A) of the FDCA [21 United States Code (USC) 351(a)(2)(A)]. For example, there were poor aseptic practices, including an operator not disinfecting or changing gloves prior to introducing them into an ISO 5 area from an ISO 7 area and after touching non-sterile material. Multiple operators with non-sterile gowning and exposed their facial skin were observed leaning into the ISO 5 work area. AIS also exposed stock solutions, intended to be sterile, to lower than ISO 5 quality air. This included the storage of said solutions in an unclassified area for further use after the container closure system had been punctured multiple times, and therefore compromised, throughout the assigned expiry period. It is a prohibited act under Section 301(k) of the FDCA to do any Act with respect to a drug if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

In order to maintain 503A exempt status, AIS must:

- Comply with the standards and guidelines in USP, Chapters 797 and 800 (collectively “USP Standards”).
- Comply with state board of pharmacy regulations.
- Compound sterile medications must be dispensed as patient specific

Other requirements include (i) labeling in compliance with the Drug Quality and Security Act (“DQSA”), and (ii) registration with each state board of pharmacy and Drug Enforcement Agency (“DEA”).

The DEA license for AIS’ Dallas facility was filled out in Relator’s name with his e-signature without his knowledge or approval.

16. By virtue of the foregoing, AIS has materially failed to adhere to the USP Standards as well as sanitary and sterile conditions described and required herein. As such, it is not exempt under Section 503A. The violations described herein are significant, systematic and

substantial and have given rise to actual discrepancies in the composition or functioning of the drugs, giving rise to FCA liability on the part of AIS.

17. In addition, some compounding deficiencies by AIS can affect, and have affected, the strength, purity and quality of the drugs essentially rendering them “worthless” and not eligible for payment by the Government.

18. Separate and apart from its conduct referred to in paragraphs 5 through 17, AIS also engaged in a scheme to increase referrals from health care providers by offering the payment of fees to sit on its Medical Advisory Boards (“MABs”) in violation of the Federal Anti-Kickback Act, 42 U.S.C. § 1320 et seq., (“AKA”). Essentially, AIS caused false claims to be submitted to the United States by inducing healthcare providers to prescribe AIS compounded drug medication for reimbursement from federal and state healthcare payors in violation of the AKA. Specifically, AIS uses MABs to purportedly gather information from its physician members. AIS used MABs not for any legitimate educational program for the medical community and the pharmaceutical companies, but instead used MABs, which lacked educational merit, to induce providers, by conferring payments and other benefits to providers prescribing their products. Purported meetings of the MABs were accompanied by other inducements shall as free travel, lodging and meals.

19. AIS’s actions in regard to MABs violated the express and implied certifications by AIS of compliance with applicable law in violation of the FCA. The violations and false certifications are material and were made by AIS knowingly.

II. THE PARTIES

A. Relator

20. Relator Jonathan Hamer was hired in early 2018 and served as Director of Pharmacy and eventually PIC of AIS, Dallas facility from its opening through summer of 2021. He was then promoted to the executive side and no longer in the pharmacy. Relator had asked to no longer be in the legal designation of PIC due to significant compliance, quality and legal issues that were not prioritized or addressed appropriately for him to feel comfortable in that role.

21. By March 2022, AIS' Dallas facility was in significant disarray as multiple staff had resigned over compliance and workplace conditions. Relators' employment was then terminated by AIS in March 2022 under the pretext of a "reduction in work force."

B. AIS

22. Bond Pharmacy, Inc., is a Delaware corporation, operating under the assumed name of as Advanced Infusion Solutions ("AIS"). AIS has offices at 623 Highland Colony Pkwy., Suite 100, Ridgeland, Mississippi 39157- 6077 and 18451 Dallas Parkway, Suite 150, Dallas, Texas 75287.

23. AIS is a provider of TDD and infusion care, in the latter case as a home infusion therapy service provider. Previously, AIS had also provided ophthalmic services.

24. AIS provides patients with a specific subset of infusion therapy by administering and dispensing compounded drug medication through implantable intrathecal pumps. Intrathecal pumps are surgically placed under a patient's skin and filled with medication that the pump delivers through a catheter to the intrathecal space of the spinal column. These pumps can infuse

the patient's medication daily for up to 120 days and routinely even longer than 120 days before needing to be refilled.

25. AIS is licensed to operate in all 50 states. AIS offers patient-specific, in-home pump care and care coordination services as well as intravenous ("IV") and subcutaneous ("SubQ") immunoglobulin therapies. Relevant here is AIS' intrathecal TDD. Relator was hired to operate AIS' Dallas TDD operation.

III. JURISDICTION

26. This action arises under the FCA, 31 U.S.C. § 3729 et seq., and the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 1345.

27. This Court also has supplemental jurisdiction over the claims brought by Relator on behalf of the State Plaintiffs under their state FCAs, pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b), and pursuant to 28 U.S.C. § 1367(a) also over Relator's individual claims.

IV. VENUE

28. Venue in this district is proper pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1391(b) and (c) since AIS transacts business in this district and/or one or more of the acts at issue occurred in this district.

V. FEDERAL AND STATE LAWS

A. The Federal Health Care Programs

29. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (“Medicare”), is a health insurance program administered by the United States that is funded by federal taxpayer revenue. The program is overseen by the United States Department of Health and Human Services (“HHS”). Medicare is a health insurance program that provides for the payment of prescription drugs, hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of Medicare.

30. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396-1396v (“Medicaid”), is a health insurance program administered by the United States and the various individual States and is funded by state and federal taxpayer revenue. The Medicaid Program is overseen by HHS. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

31. The Civilian Health and Medical Program of the Uniformed Services (“CHAMPUS”) (now known as “TRICARE”), 10 U.S.C. §§ 1071-1106, et seq. provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the uniformed services of the United States and to spouses and children of active duty, retired and deceased members of such uniformed services. The program is administered by the United States Department of Defense and funded by the United States. TRICARE pays for, among other items and services, prescription drugs for its beneficiaries.

32. The United States, through its Departments of Defense and Veterans Affairs, Bureau of Prisons, Native and American Indian Health Services, and Public Health Service maintains and operates medical facilities, including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise.

33. The Federal Employees Health Benefits Program (“FEHBP”) provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. Together the programs described in paragraphs 29 through 32 shall be referred to as “Federal Health Care Programs” or “Government Health Care Programs.”

B. The False Claims Act

34. The FCA, 31 U.S.C. § 3729(a)(1),² makes “knowingly” presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty.

35. The FCA, 31 U.S.C. § 3729(a)(2), makes “knowingly” making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the United States sustains and a civil monetary penalty.

² On May 22, 2009, the Fraud Enforcement and Recovery Act (“FERA”) was enacted into law which, inter alia, amended the False Claims Act. Part of the amendment renumbered certain sections. Under FERA, effective May 22, 2009 3729(a)(1) became 3729(A)(1). Likewise, 3729(a)(2) became 3729(A)(2) and 3729(a)(3) became 3729(A)(3) . Since the allegations include a time period before and after May 22, 2009, references are to be applicable sections.

36. The FCA defines a “claim” to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States provides any portion of the money or property which is requested or demanded, or if the United States will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

C. The State False Claims Acts

37. As specified above, the State Plaintiffs have enacted state false claims acts similar to the FCA, permitting a private person such as Relator to bring suit to recover on behalf of each of the States from persons that knowingly submit false claims to the States or engage in related misconduct, and providing for awards to a private person bringing the action if the States prevail in the actions.

38. As set forth below, several states have passed false claims acts (the “State False Claims Acts”) legislation, which in most instances closely tracks the Federal FCA. These include the following states: The State Of California, The State Of Delaware, The State Of Florida, The State Of Georgia, The State Of Hawaii, The State Of Illinois, The State Of Indiana, The State Of Louisiana, The State Of Michigan, The State Of Montana, The State Of Nevada, The State Of New Jersey, The State Of New Mexico, The State Of New York, The State Of Oklahoma, The State Of Rhode Island, The State Of Tennessee, The State Of Texas, The State Of Wisconsin, The Commonwealth Of Massachusetts, The Commonwealth Of Virginia, The District Of Columbia, The City Of Chicago, The State Of Connecticut, The State Of Colorado, The State Of Maryland, The State Of Iowa, And The State Washington. These State False Claims Acts apply to the state portion of Medicaid fraud losses caused by false Medicaid claims within the joint federal-state funded Medicaid program. Each of the statutes listed above contains *qui tam*

provisions of the State False Claims Acts governing, *inter alia*, a relator's right to claim a share of a state's recovery.

D. Section 503A of the FDCA

39. Section 503A, added to the FDCA by the Food and Drug Administration Modernization Act of 1997 and amended by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemption from the FDCA.

40. As described herein previously. Section 503A sets forth certain conditions that must be satisfied for compounded drugs to be exempt from the vast regulatory framework that would otherwise govern new drugs.

41. AIS has obtained licenses in all 50 states representing itself in the license applications and registration as meeting the conditions to be a Section 503A pharmacy. As such, AIS as a 503A facility must compound its drug products in accordance to patient specific prescriptions and is required by the state boards of pharmacy to comply with USP Standards previously described.

E. The Anti-Kickback Statute

42. The Medicare, Medicaid and Anti-Kickback Act (“AKA”) 42 U.S.C. §1320a-7b(b), makes it illegal to:

offer, receive, or solicit any remuneration, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order to induce such person to purchase, lease, or order, or to arrange for or recommend the purchasing, leasing, or ordering of any good, service, or item for which payment may be made in whole or in part under a Federal Health Care Program.

Many states have similar laws pertaining to the Medicaid program.

43. The AKA has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Kats*, 871 F.2d 105, 108 (9th Cir.1989); *United States v. Greber*, 760 F.2d 68, 69 (3d Cir.1985); see *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir.1989) (“The key to a Medicare Fraud case is the reason for the payment—was the purpose of the payments primarily for inducement.”)

44. Congress prohibits pharmaceutical companies from compensating healthcare providers to induce them to prescribe often more expensive drugs paid by federal and state treasuries. Mindful of this bar, marketing to persuade healthcare providers to serve on their internal advisory boards may violate the AKA.

45. Preservation of the public fisc would be undermined if a provider could engage in conduct warranting exclusion from the program altogether yet still demand payment until the time of formal exclusion.

46. The AKA is intended not only to prohibit but also to prevent such fraudulent conduct. The AKA’s “legislative history also suggests a deterrent, and thus punitive, purpose.”

H.R. Rep. No. 95-393, pt. 2, at 44, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3040, 3047, 3050 (stating that the AKA was enacted to “strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs”). If providers could demand payment for claims resulting from kickback violations, then the AKA would be meaningless legislation.

47. Compliance with the AKA clearly factors into the government's reimbursement decision; not only is the government unwilling to pay a claim that is the product of criminal conduct under the AKA, but also to submit such a claim for reimbursement is in effect to ask the government to fund criminality retroactively, a result specifically proscribed by the AKA. *See* 42 U.S.C. § 1320a-7b(b).

VI. ALLEGATIONS OF THE FALSE CLAIMS

A. The Deficiencies at the AIS Dallas Facility

48. The AIS Dallas facility was built on non-sealed porous ground. The Chief Quality Officer (“CQO”), who at the time was the Chief Operating Officer (“COO”), Michael Ford (“Ford”), was aware of this significant problem. Instead of correcting the condition, Ford directed the contractor to proceed and signed off on a waiver absolving the contractor of any liability when this problem was brought to his attention.

49. Relator learned from several of the original construction crew and engineers as well as clean room specialists that Ford was told water would seep through the ground into the Dallas facility. These concerns were dismissed by senior management at AIS for years.

50. As warned, water, sewage, and mold seeped through the floor of the Dallas facility, causing putrid odor and bubbling of the floor. Not only is this considered an “insanitary

condition” according to the FDA, to continue to compound medication, this may have contributed to reported patient illnesses during this time and which have never been disclosed.

51. Sewer waste has continuously been backed up into the AIS Dallas facility on multiple occasions and then covered up. It is a well-known occurrence that at certain times of day and certain temperatures, the facility reeked of human waste.

52. Much like the floor, the walls of the clean room at the Dallas facility were disintegrating for months, creating another “an insanitary condition,” during the compounding of many syringes.

53. In addition to informing AIS management of the problems referred to in paragraphs 48 through 52, Relator also reported the sanitary conditions to outside consulting/inspections groups so that they would put it in their report to force leadership to deal with it.

54. At the AIS Dallas Facility, there were and still are material violations of USP Standards Chapter 795, 797 and 800. These include:

1. Clothes and gloves are not inspected for rips and tears routinely during compounding.

2. There is no complete physical separation, either fixed or non-fixed, of areas where blood products are handled from areas where non-blood products are handled. This is particularly egregious where compounding activities require the manipulation of a patient's blood or other biological matter.

3. The airflow visualization studies performed by Air Safe on February 2, 2021 demonstrated that airflow was not shown from the entry point (approximately an

inch below the HEPA filter diffuser screen) and airflow was not shown from the above IV bar to the direct compounding area.

4. Training at the AIS Dallas facility does not comply with OSHA 1910.120.

5. There is no policy or procedure for spill management.

6. The work surfaces of the CPEC are often contaminated between the compounding of different HDs and in between compounding serums. The purpose of the decontamination is to reduce the likelihood that patients will be exposed to HDs other than those that are prescribed to them or being exposed to serum that is not theirs. This is not currently occurring nor is it prescribed.

7. There is a failure to properly label, pack, and transport the disposals of Hds.

B. Compounding of Commercially Available Products

55. One of the conditions that must be met for a compounded drug product to qualify for exemption under Section 503A of the FDCA is that it must be compounded by a licensed pharmacist or a licensed physician who “does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.” The statute further states that “the term ‘essentially a copy of a commercially available drug product’ does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug.”

56. Relator verbally and in writing raised concerns that AIS compounded drug medications were “essentially copies of commercially available medications,” as defined by the

FCA, after Relator joined AIS. Specifically, Relator objected to AIS management that they, in essence operating improperly as a 503B Facility for which they were not licensed. Examples of these drugs were, inter alia, morphine sulfate, fentanyl citrate, and hydromorphone HCl. These included the same patients getting prescriptions as many as eight times for “one-time eye surgeries.”

57. Drug products were compounded at >1000x the amount needed to serve AIS customers.

C. Illegal Kickbacks as an Inducement to Providers

59. On paper, AIS implemented MABs to “create an intimate forum where compounding issues, clinical data, and patient care could be debated.”

60. In practice, however, AIS used MABs as a “sales tactic” to expand AIS's market presence. AIS paid doctors to attend MABs and offered valuable meals and entertainment.

61. AIS invited “targeted physicians” from “key accounts” to attend advisory boards.

62. AIS controlled the content of MABs. AIS used MABs as an opportunity to market its products instead of allowing doctors to freely discuss clinical data and patient care.

63. AIS violated the AKA by paying doctors kickbacks to prescribe its compounded drug medications, for which the doctors submitted claims for payment to the federal government. AIS’s scheme involved offering or paying "remuneration." At least one purpose of the scheme was to "induce" doctors to prescribe more and AIS possessed the requisite scienter.

VII. THE FCA AND FALSE CERTIFICATIONS

A. Implied Certification

65. The FCA is "intended to reach all types of fraud, without qualification, that might result in financial loss to the government." *United States v. Neifert White*, 390 U.S. 228, 232 (1968). Relator alleges that AIS violated the FCA by causing the submission of false claims³ all in violation of 31 U.S.C. § 3729(a)(1) (A) and (B).

66. A legally false FCA claim is based on a 'false certification' theory of liability." A claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation which is material to the government's decision whether to make payment for the goods or services.

67. Within the theory of false certification, there are two further categories: express and implied false certification. A defendant violates the FCA by express false certification when, in conjunction with a request for federal funds, it certifies that it is in compliance with regulations that are requirements for payment.

68. An FCA violation occurs under implied false certification when a Defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose noncompliance with a statutory, regulatory or a contractual requirement. In these circumstances, liability may attach if the omission renders

³ The FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

those representations misleading. This is substantially the same scenario and facts presented.

United States ex rel. Escobar, 579 U.S. ___, 2016 WL 3317565, slip op., No.

15-7 (June 16, 2016).

69. The false statements contained in AIS certifications as to its eligibility and compliance with Section 503A to the FDA and state pharmacy boards and with the USP Standards represents a false implied certification.

70. A false certification (express or implied) establishes the “falsity” of a claim under the FCA. This was emphasized by Congress in the 1986 Amendments to the FCA, stating “each and every claim submitted under a contract, loan guarantee or other agreement which was originally obtained by means of false statements or other corrupt and fraudulent conduct, or in violation of any statute or appropriate regulation, constitutes a false claim.” S.Rep. No. 99-345 at 9 (1986), reprinted in 1986 U.S.C.C.A.M. 5266, 5274.

71. Section 3729(a)(1)(A) requires only that a claimant present a ‘false or fraudulent claim for payment or approval’ without the additional element of a ‘false record or statement.’ *Id.* Thus, § 3729(a)(1)(A) allows a relator to bring a claim based on a defendant submitting a claim for government funds without explicitly making a false statement.

B. Express Certification

72. The Medicare program requires approved providers to expressly and affirmatively certify that they have complied with the AKA. Failure to comply with the AKA, therefore, is, in and of itself, a false statement to the government.

73. Federal courts have determined in any case that compliance with the AKA is a precondition of payment. This conclusion is “rendered inescapable when the purpose of the AKA is considered within the context of the Medicare statute.” 42 U.S.C. § 1395y(a)(1)(A).

Moreover, courts, without exception, agree that compliance with the AKA is a precondition of Medicare payment, such that liability under the FCA can be predicated on a violation of the AKA.⁴

74. Medicare regulations and the CMS Provider Agreement expressly provide that certification is a precondition to governmental reimbursement. In order to obtain reimbursement, and as a condition to payment, providers must certify that they are in compliance with the terms of the Provider Agreement.

75. AIS has maintained billing privileges with Medicare and has entered into a Provider Agreement CMS Form 855s. This Provider Agreement contains a certification that each provider must certify as follows:

“... I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier’s compliance with all applicable conditions of participation in Medicare.”

76. AIS’ actions violate the Federal FCA, 31 U.S.C. § 3729(a)(2) and § 3729(a)(1)(B) in that AIS knowingly and falsely certified that it had complied with the AKA in order to get claims paid by Federal Health Care Programs.

⁴ See, e.g., *Willis v United Health Group*, 2011 WL 2573380 (2011), (“Compliance with the [AKA] is clearly a condition of payment under Parts C and D of Medicare); *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir.2009) (“Falsely certifying compliance with the ... Anti-Kickback Act[] in connection with a claim submitted to a federally funded insurance program is actionable under the [False Claims Act].”); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir.2004) (“A certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program.”)

VIII. CAUSES OF ACTION

A. Count One

The FCA: 31 U.S.C. § 3729(a)(1)(A)

77. The allegations of paragraphs 1-76 are incorporated herein as if more fully set forth at length.

78. The FCA, 31 U.S.C. § 3729(a)(1)(A) makes “knowingly” presenting or causing to be presented to the United States any false or fraudulent claim for payment a violation of federal law for which the United States may recover three times the amount of the damages the United States sustains and a civil monetary penalty of between \$10,781 and \$21,563 per claim.

79. The false statements by AIS regarding compliance with the AKA were an express false certification made by AIS in the claims submissions as well as in CMS Form 885A and CMS Form 1500.

B. Count Two

The FCA: 31 U.S.C. § 3729(a)(1)(B)

80. The allegations of paragraphs 1-79 are incorporated herein as if more fully set forth at length.

81. The FCA, 31 U.S.C. § 3729(a)(1)(B) makes “knowingly” making, using or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of \$10,781 and \$21,563.

82. The false statement contained in AIS’ State Pharmacy Board applications and registrations regarding USP Standards and Section 503A was submission of a false record.

C. Count Three

Hamer v. AIS – 31. U.S.C. § 3730(h)

83. The allegations of paragraphs 1-82 are incorporated herein as more fully set forth at length.

84. Plaintiff was terminated in May 2022 within several weeks of making one or more of such complaints to one or more human resources representatives or in-house counsel for Defendant.

85. Also during his employment, in April 2022, Plaintiff was injured at work by exposure to cleaning solvents, suffering injury to his lungs, constituting a disability as an impairment of his major bodily function of respiration.

86. Apart from the actions and omissions of Defendant reflecting retaliation against Plaintiff on the basis of his opposition to practices of Defendant violating the FCA, Plaintiff, during his employment by Defendant, was subjected to discrimination on the basis of religion and disability, and to retaliation, in violation of Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act and the Texas Labor Code, under the following circumstances:

87. During his employment, Plaintiff was repeatedly subjected to questions and bigoted statements and conduct of representatives of Defendant based on his Jewish religion. Plaintiff complained of such anti-Semitism by representatives of Defendant to one or more human resources representatives of Defendant and also complained to one or more human resources representatives or in-house counsel for Defendant, or both, of sexual harassment by a representative of Defendant at a work function as well as racist and homophobic comments by representatives of Defendant at other times. Plaintiff further complained to one or more human resources representatives or in-house counsel for Defendant, or both, of derogatory statements on

the basis of race about his wife and other employees of Defendant by representatives of Defendant. Plaintiff was terminated in May 2022 within several weeks of making one or more of such complaints to one or more human resources representatives or in-house counsel for Defendant.

88. Also during his employment, after Plaintiff was injured at work by exposure to cleaning solvents, suffering injury to his lungs, constituting a disability as an impairment of his major bodily function of respiration, Plaintiff complained and requested accommodation in the form of a respirator and otherwise, including after suffering additional injury in the course of continuing to work, as instructed by his superior, at the risk of impairment of his respiratory function, but the accommodations were denied and he was terminated within two weeks of his last report of disability and request for accommodations.

D. Count Four

Violations of the California FCA by Defendant

89. Defendants violated the California FCA in the following respects:

- a. California Government Code §12651(a)(1) prohibits a person from knowingly presenting or causing to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval.
- b. California Government Code §12651(a)(2) prohibits a person from knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the state;
- c. California Government Code §12651(a)(3) prohibits a person from conspiring to defraud the state by getting a false claim allowed or paid by the state; and

d. California Government Code §12651(a)(7) prohibits a person from knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the state.

E. Count Five

Violations of the Delaware FCA by Defendant

90. Defendants violated the Delaware FCA in the following respects:

a. The Defendants violated the Delaware FCA §1201(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Delaware a false or fraudulent claim for payment or approval;

b. Defendants violated Delaware FCA §1201(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware;

c. Defendants violated Delaware FCA §1201(a)(3) by conspiring to defraud the State of Delaware by getting a false or fraudulent claim allowed or paid;

d. Defendants violated Delaware FCA §1201(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Delaware.

F. Count Six

Violations of the Florida FCA by Defendant

91. Defendants violated the Florida FCA in the following respects:

a. Defendants violated §68.082(2)(a) by knowingly presenting or causing to be presented to an officer or employee of the State of Florida a false or fraudulent claim for payment or approval;

- b. Defendants violated §68.082(2)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida;
- c. Defendants violated §68.082(2)(c) by conspiring to defraud the State of Florida by getting a false or fraudulent claim allowed or paid;
- d. Defendants violated §68.082(2)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida.

G. Count Seven

Violations of the Georgia FCA by Defendant

- 92. Defendants violated the Georgia FCA in the following respects:
 - a. Defendants violated O.C.G.A. §49-4-168.1(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Georgia a false or fraudulent claim for payment or approval;
 - b. Defendants violated O.C.G.A. §49-4-168.1(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia;
 - c. Defendants violated O.C.G.A. §49-4-168.1(a)(3) by conspiring to defraud the State of Georgia by getting a false or fraudulent claim allowed or paid;
 - d. Defendants violated O.C.G.A. §49-4-168.1(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia.

H. Count Eight

Violations of the Hawaii FCA by Defendant

93. Defendants violated the Hawaii FCA in the following respects:

- a. Defendants violated H.R.S. Section 661.21(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Hawaii a false or fraudulent claim for payment or approval;
- b. Defendants violated H.R.S. Section 661.21(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii;
- c. Defendants violated H.R.S. Section 661.21(a)(3) by conspiring to defraud the State of Hawaii by getting a false or fraudulent claim allowed or paid;
- d. Defendants violated H.R.S. Section 661.21(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii.

I. Count Nine

Violations of the Illinois FCA by Defendant

94. Defendants violated the Illinois FCA in the following respects:

- a. Defendants violated 740 ILCS 175/3(a)(1)(A) by knowingly presenting or causing to be presented to an officer or employee of the State of Illinois a false or fraudulent claim for payment or approval;
- b. Defendants violated 740 ILCS 175/3 (a)(1)(B) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois;

- c. Defendants violated 740 ILCS 175/3 (a)(1)(c) by conspiring to commit a violation of subparagraphs (A), (B), or (G);
- d. Defendants violated 740 ILCS 175/3 (a)(1)(G) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Illinois.

J. Count Ten

Violations of the Indiana FCA by Defendant

- 95. Defendants violated the Indiana FCA in the following respects:
 - a. Defendants violated I.C.5-11-5.5-2(b)(1) by knowingly presenting a false claim to the State of Indiana for payment or approval;
 - b. Defendants violated I.C. 5-11-5.5-2(b)(6) by knowingly making or using a false record or statement to obtain payment or approval of a false claim from the State of Indiana;
 - c. Defendants violate I.C. 5-11-5.5-2 (b)(6) by making or using a false record or statement to avoid an obligation to pay the State of Indiana.
 - d. Defendants violated I.C. 5-11-5.5-2 (b)(7) by knowingly conspiring with another person to perform any of those acts described in (a), (b), and (c) above.

K. Count Eleven

Violations of the Louisiana FCA by Defendant

- 96. Defendants violated the Louisiana FCA in the following respects:
 - a. Defendants violated RS 46:438.3A by knowingly presenting or causing to be presented a false or fraudulent claim;

- b. Defendants violated RS 46:438.3B by knowingly engaging in misrepresentation or making, using, or causing to be made or used, a false record or statement to obtain payment for a false or fraudulent claim from the Louisiana Medicaid program;
- c. Defendants violated RS 46:438.3C by knowingly making, using, or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay money to the Louisiana Medicaid program;
- d. Defendants violated RS 46:438.3D by conspiring to defraud, or attempt to defraud, the Louisiana Medicaid program through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;
- e. Defendants violated RS 46.438.2A(2) by soliciting, receiving, offering, or paying remuneration, including but not limited to kickbacks, bribes, rebates, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, leasing, or ordering, any good, supply, service or facility for which payment may be made, in whole or in part, under the Louisiana Medicaid program.

L. Count Twelve

Violations of the Michigan FCA by Defendant

97. Defendants violated the Michigan FCA in the following respects:
- a. Defendants violated MCL 400.607(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Michigan a claim under the social welfare act, upon or against the state, knowing the claim to be false;
 - b. Defendants violated MCL 400.604 by knowingly soliciting, offering, or receiving a kickback or bribe in connection with the furnishing of goods or services for which payment is

or may be made in whole or in part pursuant to a program established under Act No. 280 of the Public Acts of 1939, as amended;

- c. Defendants violated MCL 400.606(1) by entering into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim under the social welfare act;
- d. Defendants violated MCL 400.607(3) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Michigan pertaining to a claim presented under the social welfare act.

M. Count Thirteen

Violations of the Montana FCA by Defendant

- 98. Defendants violated the Montana FCA in the following respects:
 - a. Defendants violated MCA 17-8-403(1)(a) by knowingly presenting or causing to be presented to an officer or employee of the State of Montana a false or fraudulent claim for payment or approval;
 - b. Defendants violated MCA 17-8-403(1)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana;
 - c. Defendants violated MCA 17-8-403(1)(c) by conspiring to commit a violation of subparagraphs (a), (b), or (g);
 - d. Defendants violated MCA 17-8-403(1)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana.

N. Count Fourteen

Violations of the Nevada FCA by Defendant

99. Defendants violated the Nevada FCA in the following respects:
- a. Defendants violated NRS 357.040(1)(a) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;
 - b. Defendants violated NRS 357.040(1)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada;
 - c. Defendants violated NRS 357.040(1)(c) by conspiring to commit a violation of subparagraphs (a), (b), or (g);
 - d. Defendants violated NRS 357.040(1)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada.

O. Count Fifteen

Violations of the New Jersey FCA by Defendant

100. Defendants violated the New Jersey FCA in the following respects:
- a. violated the New Jersey FCA §2A:32C-3a by knowingly presenting or causing to be presented to an officer or employee or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
 - b. Defendants violated New Jersey FCA §2A:32C-3b by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey;

- c. Defendants violated New Jersey FCA §2A:32C-3c by conspiring to defraud the State by getting a false or fraudulent claim allowed or paid by the State;
- d. Defendants violated New Jersey FCA §2A:32C-3g by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

P. Count Sixteen

Violations of the New Mexico FCA by Defendant

- 101. Defendants violated the New Mexico FCA in the following respects:
 - a. violated NMSA §27-14-4A by presenting or causing to be presented to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;
 - b. Defendants violated NMSA §27-14-4C by making, using or causing to be made or used a false record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
 - c. Defendants violated NMSA §27-14-4D by conspiring to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent;
 - d. Defendants violated NMSA §27-14-4E by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State, relative to the Medicaid program, knowing that such record or statement is false.

Q. Count Seventeen

Violations of the New York FCA by Defendant

102. The Defendants violated the New York FCA in the following respects:

- a. The Defendants violated State Fin. Law §189.1(a) by knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval;
- b. The Defendants violated State Fin. Law §189.1(b) by knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim;
- c. The Defendants violated State Fin. Law §189.1(c) by conspiring to commit a violation paragraph (a), (b) or (g) of this subdivision;
- d. The Defendants violated State Fin. Law §189.1(g) by knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state.

R. Count Eighteen

Violations of the Oklahoma FCA by Defendant

103. Defendants violated the Oklahoma FCA in the following respects:

- a. Defendants violated Okla. Stat. §63-5053.1(B)(1) by knowingly presenting or causing to be presented to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
- b. Defendants violated Okla. Stat. §63-5053.1(B)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the state;
- c. Defendants violated Okla. Stat. §63-5053.1(B)(3) by conspiring to defraud the state by getting a false or fraudulent claim allowed or paid;

d. Defendants violated Okla. Stat. §63-5053.1(B)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.

S. Count Nineteen

Violations of the Rhode Island FCA by Defendant

104. Defendants violated the Rhode Island FCA in the following respects:

a. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(1) by knowingly presenting or causing to be presented to an officer or employee of the state or member of the guard a false or fraudulent claim for payment or approval;

b. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(2) by knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the state;

c. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(3) by conspiring to defraud the state by getting a false or fraudulent claim allowed or paid;

d. Defendants violated R.I. Gen. Laws § 9-1.1-3(a)(7) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.

T. Count Twenty

Violations of the Tennessee FCA by Defendant

105. Defendants violated the Tennessee FCA in the following respects:

a. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(A) by presenting or causing to be presented to the state a claim under the Medicaid program knowing such claim is false or fraudulent;

- b. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(B) by making, using or causing to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid or approved by the state knowing such record or statement is false;
- c. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(C) by conspiring to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;
- d. Defendants violated Tenn. Code Ann. §71-5-181(a)(1)(D) by making, using or causing to be made or used, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing such record or statement is false.

U. Count Twenty-One

Violations of the Texas FCA by Defendant

106. Defendants knowingly or intentionally reported to the State of Texas' Medicaid Program false statements or misrepresentations regarding their pharmaceutical products. These actions were repeated and continuous violations of the Texas Medicaid Fraud Prevention Act ("TMFPA").

107. Defendants violated the TMFPA in the following respects:
- a. Section 36.002(1) prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of material fact on an application for a contract, benefit, or payment under the Medicaid Program; or that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program;
 - b. Section 36.002(2) prohibits a person from knowingly or intentionally concealing or failing to disclose an event that permits a person to receive a benefit or payment that is not

authorized, or that permits a person to receive a benefit or payment that is greater than the benefit or payment that is authorized;

c. Section 36.002(4) prohibits a person from knowingly or intentionally making or causing to be made a false statement or misrepresentation of fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program;

d. Section 36.002(5) prohibits a person, except as authorized under the Medicaid program, from knowingly paying, charging, soliciting, accepting, or receiving, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program; and

e. Section 36.002(9) prohibits a person from knowingly entering into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent.

V. Count Twenty-Two

Violations of the Wisconsin FCA by Defendant

108. Defendants violated the Wisconsin FCA in the following respects:

a. Defendants violated Wis. Stat. §20.931(2)(a) by knowingly presenting or causing to be presented to an officer, employee, or agent of the state a false claim for medical assistance;

b. Defendants violated Wis. Stat. §20.931(2)(b) by knowingly making, using or causing to be made or used a false record or statement to get a false claim paid for medical assistance;

- c. Defendants violated Wis. Stat. §20.931(2)(c) by conspiring to defraud the state by obtaining allowance or payment of a false claim for medical assistance or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program;
- d. Defendants violated Wis. Stat. §20.931(2)(g) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

W. Count Twenty-Three

Violations of the Massachusetts FCA by Defendant

109. Defendants violated the Massachusetts FCA in the following respects:
- a. Defendants violated Mass. Gen. Laws Ch. 12, §5B(1) by knowingly presenting or causing to be presented a false claim for payment or approval;
 - b. Defendants violated Mass. Gen. Laws Ch. 12, §5B(2) by knowingly making, using or causing to be made or used a false record or statement to obtain payment or approval of a claim by the commonwealth;
 - c. Defendants violated Mass. Gen. Laws Ch. 12, §5B(3) by conspiring to defraud the commonwealth through the allowance or payment of a fraudulent claim;
 - d. Defendants violated Mass. Gen. Laws Ch. 12, §5B(8) by knowingly making, using or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the commonwealth.

X. Count Twenty-Four

Violations of the Virginia FCA by Defendant

110. Defendants violated the Virginia FCA in the following respects:

- a. Defendants violated Code of Virginia § 8.01-216.3A(1) by knowingly presenting, or causing to be presented, to an officer or employee of the Commonwealth a false claim for payment or approval;
- b. Defendants violated Code of Virginia § 8.01-216.3A(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
- c. Defendants violated Code of Virginia § 8.01-216.3A(3) by conspiring to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;
- d. Defendants violated Code of Virginia § 8.01-216.3A(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth.

Y. Count Twenty-Five

Violations of the District of Columbia FCA by Defendant

111. Defendants violated the District of Columbia FCA in the following respects:

- a. Defendants violated D.C. Code Ann., 2-308.14(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the District a false claim for payment or approval;
- b. Defendants violated D.C. Code Ann., 2-308.14(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false claim paid or approved by the District;

- c. Defendants violated D.C. Code Ann., 2-308.14(a)(3) by conspiring to defraud the District by getting a false claim allowed or paid by the District;
- d. Defendants violated D.C. Code Ann., 2-308.14(a)(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District.

Z. Count Twenty-Six

Violations of the Chicago FCA by Defendant

112. Defendants violated the Chicago FCA in the following respects:
- a. Defendants violated Mun. Code of Chicago 1-22-020(1) by knowingly presenting, or causing to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval;
 - b. Defendants violated Mun. Code of Chicago 1-22-020(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District;
 - c. Defendants violated Mun. Code of Chicago 1-22-020(3) by conspiring to defraud the District by getting a false claim allowed or paid by the city;
 - d. Defendants violated Mun. Code of Chicago 1-22-020(7) by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the city.

AA. Count Twenty-Seven

Violations of the Connecticut FCA by Defendant

113. Defendants violated the Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-301 through 17b-301p (“Connecticut FCA”) in the following respects:

- a. Defendants violated the Connecticut FCA by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;
- b. Defendants violated the Connecticut FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
- c. Defendants violated the Connecticut FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;
- d. Defendants violated the Connecticut FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

BB. Count Twenty-Eight

Violations of the Maryland FCA by Defendant

114. Defendants violated the Maryland Health False Claims ACT, as amended by Maryland Laws Ch. 66. Title 2, Subchapter 6, § 2-601 to § 2-610 (“Maryland FCA”) in the following respects:

- a. Defendants violated the Maryland FCA by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;
- b. Defendants violated the Maryland FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

- c. Defendants violated the Maryland FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;
- d. Defendants violated the Maryland FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

CC. Count Twenty-Nine

Violations of the Washington FCA by Defendant

115. Defendants violated the Washington Medicaid Fraud False Claims Act, WASH. SESS. LAWS, LAWS OF 2012, Ch. 241 §§ 201 through 214 (“Washington FCA”) in the following respects:

- a. Defendants violated the Washington FCA, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;
- b. Defendants violated the Washington FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
- c. Defendants violated the Washington FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;
- d. Defendants violated the Washington FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

DD. Count Thirty

Violations of the Colorado FCA by Defendant

116. Defendants violated the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310 (“Colorado FCA”) in the following respects:
- a. Defendants violated, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;
 - b. Defendants violated the Colorado FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
 - c. Defendants violated Colorado FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;
 - d. Defendants violated Colorado FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

EE. Count Thirty-One

Violations of the Iowa FCA by Defendant

117. Defendants violated the Iowa False Claims Act (“Iowa FCA”) Iowa Code §§ 685.1 through 685.7 in the following respects:
- a. Defendants violated Iowa FCA, by knowingly presenting, or causing to be presented, to an official or employee of the State a false or fraudulent claim for payment or approval;

- b. Defendants violated the Iowa FCA by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
- c. Defendants violated Iowa FCA by conspiring to defraud the District by getting a false claim allowed or paid by the State;
- d. Defendants violated the Iowa FCA by knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

IX. RELIEF REQUESTED

118. Relator requests the following relief be imposed against Defendant:

- (a) That the United States be awarded three times the amount of damages which it sustained because of the acts of Defendant pursuant to §3729(a)(1)(A) through C of the FCA;
- (b) That Defendant be held liable for civil penalties up to \$21,563 but not less than \$10,781 (as adjusted pursuant to § 3729 of the FCA and the Civil Penalties Act), to the United States for every act in violation of the FCA;
- (c) That this Court award such interest as is available pursuant to the FCA.
- (d) That in the event the United States intervenes in this action and takes over its prosecution, the Relator be awarded an amount for bringing this action on behalf of the United States of at least 15% but not more than 25% of the proceeds paid to the United States resulting from the trial or settlement of the claim pursuant to § 3730(d)(1) of the FCA;

- (e) That in the event the United States does not intervene in this action, the Relator be awarded an amount for bringing this action for the United States of at least 25% but no more than 30% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to § 3730(d)(2) of the FCA;
- (f) That this Court award reasonable attorneys' fees, costs and expenses to Relator which were necessarily incurred in bringing and prosecuting this case pursuant to § 3730(d)(1) or (2) of the FCA;
- (g) That this Court award Plaintiff individually all of the relief to which he is entitled described in paragraphs 83 through 88;
- (h) That all State Plaintiffs be awarded all damages and civil penalties and interest recoverable under the state statutes referred to in paragraphs 89 through 117;
- (i) That in the event of one of the State Plaintiffs does not intervene in this action, the Relator be awarded an amount for bringing this action on behalf of such states to the maximum extent provided for in the state statutes referred to in paragraphs 89 through 117.
- (j) That this Court award such other relief as it deems just, necessary and fair. Relator requests a trial by jury of all issues so triable.

Respectfully submitted,

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